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10/083,737	02/27/2002	Valerio DiTizio	7692-12 LAB	2575

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EXAMINER

BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/083,737

Applicant(s)

DITIZIO ET AL.

Examiner

Susan W Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-51 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-38 and 40-51 is/are allowed.
- 6) ☒ Claim(s) 1-17, 23-35 and 39 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-51 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 pages
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 and 23-51, drawn to a method of modifying a polymeric surface, classified in class 522, subclass 85.
- II. Claims 18-22, drawn to a polymeric composite and medical device, classified in class 428, subclass 412+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as bonding a polyacrylate film to a polymeric surface. See Fan et al (5,620,738) in column 5, lines 31-42.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or separate status in the art because of their recognized divergent subject matter, and because the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Lola A. Bartoszewicz on September 11, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17 and 23-51. Affirmation of this election must be made by applicant in responding to this Office action. Claims 18-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

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inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 23-35 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claims 1 and 23: it is not clear what is meant by an "aqueous monomer". Does applicant intend to recite an aqueous monomer solution or a monomer containing water? It is suggested that the abbreviation "UV" be replaced with "ultraviolet (UV)".

With respect to claims 4, 25 and 39, there is no antecedent basis in claim 3, claim 24 or in claim 38 for the term "silicone" since claims 3, 24 and 38 are limited to polyorganosiloxanes or polysiloxanes.

Claims 7, 28 and 42 are missing the symbol  $\alpha$  in front of "hydroxyketones".

Claims 9 and 30: Does applicant intend to recite a monomer containing photoinitiating groups as one of the monomers in the aqueous monomer (solution) or does applicant intend to set forth an aqueous solution comprising a monomer and a photoinitiator?

Claim 10: It is not clear from the claim language in claims 8-10 how the method of claim 8 differs from the method of claim 10. If applicant intends to set forth a photoinitiator with which the polymeric material in claim 1 is coated in claim 8 and a photoinitiator that is added to the aqueous monomer solution in which the photoinitiator coated polymeric material is "incubated" in claim 10, it should be so stated.

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Claims 15 and 16: there is no antecedent basis in claim 14 for the recitation in claim 15 of "prior to incubation in a silver salt". Claim 14 does not mention incubation in a silver salt. The method in claim 14 does not recite how the polymeric material is rendered antibacterial. The polymeric material according to the method of claim 14 is an antibacterial polymeric material. The method set forth in claim 15 does not clearly set forth whether it is a method for rendering the polymeric surface as described in claim 13 antibacterial or a method for treating the antibacterial polymeric surface obtained by the method of claim 14.

Claim 17: It is not clear how the polymeric material with said modified surface came to be coated with a gelatin polyethyleneoxide hydrogel having a silver salt incorporated therein. The method recited in claim 10 appears to provide a photoinitiator coated polymeric material having a polymeric coating obtained by exposing an aqueous monomer solution to UV light. See the monomers recited in claim 6. Does applicant intend to claim a method comprising coating the polymeric material having a polymeric coating as said modified surface (according to the method of claim 10) with a gelatin polyethyleneoxide hydrogel having a silver salt incorporated therein? If so, it should be so stated and the coating steps employed, such as application of the hydrogel and curing to bond the hydrogel to the polymeric material, should be set forth.

Claim 23: In the last line, there is no antecedent basis within the claim for "said ionized modified polymeric surface". No method step has been set forth to provide an ionized modified polymeric surface.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ottersbach et al (6,001,894). Ottersbach et al disclose a process for modifying a polymer surface by pretreating the polymer substrate with a photoinitiator and an ethylenically unsaturated monomer, followed by graft polymerization of the monomer optionally in the presence of additional ethylenically unsaturated monomer. See column 1, lines 1-13, column 3, lines 53-62, column 4, lines 10-67, column 6, lines 16-35, and column 8, lines 3-23 and lines 37-54, column 9, lines 15-30 and Examples 7-17. Ottersbach et al do not teach grafting a polysilicone substrate.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Chabreck et al (6,447,920, having an effective filing date of 04-28-1999). Chabreck et al disclose coating a polymeric substrate with a photoinitiator and grafting macromers to the coated substrate. Polysiloxane/perfluoropolyether copolymer is used as the substrate in the Examples. See column 4, lines 12-67, column 5, line 41, to column 9, line 30, column 23, lines 15-38, column 23, line 60, to column 24, line 5, and Examples D-1 to D-8.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al in "Surface Photografting of Hydrophilic Vinyl Monomers onto Diethyldithiocarbamated Polydimethylsiloxane", J. Appl Polym. Sci.. See the disclosure as follows: "Photografting of vinyl monomers has been studied to make hydrophilic polydimethylsiloxane (PDMS) surfaces. A chlorine-containing polydimethylsiloxane (C-PDMS) prepared by polymerization of chloromethylheptamethylcyclotetrasiloxane was photocured on a glass plate. The crosslinked C-PDMS was subjected to a reaction with sodium diethyldithiocarbamate.

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The di-ethyldithiocarbamated PDMS was then photoirradiated in the presence of hydrophilic vinyl monomers such as alpha-hydroxyethylmethacrylate and acrylamide to afford surface-grafted PDMS. Several vinyl monomers were found to graft onto the PDMS surface, as revealed by their attenuated reflectance infrared and ESCA spectra. Hydrophilicity of the grafted PDMS surfaces was confirmed by the decrease in their water contact angle.”

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikada et al, in Surface Grafting, pages 125-126. Graft polymerization of vinyl monomers such as (meth)acrylic acid on a benzophenone-coated LDPE film in aqueous medium is disclosed. Graft polymerization by irradiation of diethylthiodicarbamate coated PDMS in solutions of hydrophilic monomers is also disclosed.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulbricht et al “Novel Photochemical Surface Functionalization of Polysulfone Ultrafiltration Membranes for Covalent Immobilization of Biomolecules”. Ulbricht et al disclose coating a polysulfone with a photoinitiator and photoinitiated grafting with acrylic acid. See the Abstract.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawhney et al (5,844,016). Sawhney et al disclose a method comprising photoinitiator priming for improved adherence of gels to substrates. The substrate can be any tissue or cell surface or surface of a device to be used in the body or in contact with body fluids (column 7, lines 40-67). Sawhney et al also teach incorporating biologically active agents into the disclosed coatings and/or polymer. See column 3, lines 20-32, columns 5-6, the method step in column 9, lines 30-56, and Examples 6-8.

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*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (6,358,557, filed 09-19-1999). Wang et al disclose a method comprising exposing a substrate to an initiator, contacting the substrate with a monomer composition and grafting monomer to the substrate to provide coated articles useful as medical products. See the Abstract, column 4, lines 38-54, column 6, lines 5-14, column 7, lines 18-55, column 8, lines 17-29, column 8, lines 58-63, column 9, lines 13-51, column 10, lines 1-22 and lines 45-60, and the Examples. Silicone tubing and thermal initiation of polymerization is used in the Examples. Photoinitiators and photosensitizers which can be thermally initiated are taught. Wang et al do not mention exposure to UV light to initiate polymerization.

It would have been obvious to one skilled in the art at the time of the invention to select a photoinitiator from the initiators taught by Wang et al and to employ UV light exposure instead of heat to initiate the graft polymerization in the method disclosed by Wang et al. The reason is that activation of a photoinitiator by exposure to UV light is the art recognized method for activating a photoinitiator. See US 6,001,894, column 8, lines 21-23. One of ordinary skill in the art at the time of the invention would thus have been motivated to employ a photoinitiator and UV light in the method disclosed by Wang et al by a reasonable expectation of successfully obtaining a useful grafted substrate as taught by Wang et al because Wang et al teach that photoinitiators may be employed as the initiator. With respect to claims 4-7, it would have been obvious to one skilled in the art at the time of the invention to select a silicone



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Claims 39, 8-17 and 24-35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the combination of the step of grafting a photoinitiator-coated polymeric material with an aqueous monomer solution by exposure to UV light, rendering the modified polymeric surface lubricious by immersion in an aqueous base to ionize the surface and providing a silver agent to the ionized modified polymeric surface.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Goldberg (5,885,566) discloses a method of graft polymerization by gamma irradiation to produce hydrophilic coatings on plastic surfaces of medical devices.

Fan et al (5,620,738) disclose lubricious coatings for biomedical device substrates such as catheters, stents, etc. and processes for applying the coatings. See column 4, lines 60-65, column 5, lines 8-30. Photoinitiators are not mentioned.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 703 308 0040. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 703 308 2462. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0661.



Susan W Berman  
Primary Examiner  
Art Unit 1711

SB  
September 15, 2003